UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE LANTUS DIRECT PURCHASER ANTITRUST LITIGATION	Civil Action No. 16-12652-LTS-JGD Class Action **REDACTED VERSION** **Leave to File Granted on Dec. 7, 2021**

JOINT SUBMISSION REGARDING NON-SEE-RELATED DISCOVERY ISSUES

Pursuant to the Court's Scheduling Order (ECF No. 278) the parties, Defendants Sanofi-Aventis U.S., LLC, and Sanofi-Aventis Puerto Rico, Inc., ("Defendants" or "the defendants"), and Direct Purchaser Plaintiffs Meijer, Inc., Meijer Distribution, Inc., and FWK Holdings, LLC, ("Plaintiffs" or "the purchasers"), provide their respective positions regarding two outstanding non-SEE-related discovery issues:

1. Whether Plaintiff FWK Holdings, LLC must produce transcripts from its own depositions in five putative antitrust class actions in which it attempted to serve as a putative class representative.

2. Whether Defendant Sanofi U.S., LLC must produce documents relating to the re-negotiation of royalty rates it paid to non-party Novo Nordisk N/A.

The parties were unable to resolve their disputes regarding these two issues through the meet-and-confer process. Accordingly, these two issues are ripe for the Court's consideration and disposition.

PRODUCTION OF TRANSCRIPTS FROM FWK'S OWN DEPOSITIONS IN OTHER ANTITRUST CLASS ACTIONS

Defendants' Position

Defendants ask the Court to compel Plaintiff FWK Holdings, LLC ("FWK") to produce in response to their Supplemental Request for Production No. 7 the transcripts of FWK's own depositions in five putative antitrust class actions in which FWK attempted to serve as a class representative. FWK does not dispute that the transcripts exist or are responsive to Defendants' request. Rather, it objects that the transcripts are irrelevant and their production would be unduly burdensome and disproportionate to the needs of this case. FWK's objections are meritless.

This is not, as the Court may recall, the first putative antitrust class action in which FWK has attempted to serve as a class representative—or in which its adequacy to do so under Rule 23(a)(4) has been called into question. *See* Mem. of Decision and Order on Sanofi's Mot. to Compel, ¶ 1(a) (ECF No. 159). In fact, it is the sixth in a string of actions FWK has filed since late 2016—shortly after it was created and underwritten by its counsel to purchase an assignment of claims from a bankrupt drug wholesaler and to serve solely as a litigation vehicle. *See* Mem. of Law In Support of Defendant Sanofi-Aventis LLC's Mot. to Compel, at 2–3, 5–7 (ECF No. 138). As the Court may also recall, it was this "entangled" "personal, financial, and business relationship between FWK, FWK-associated individuals, and class counsel," among other things, that led Judge Burroughs to find that FWK could not serve as an adequate class representative in *In re Intuniv Antitrust Litig.*, No. 1:16-cv-12653-ADB, 2019 WL 4645502, at *8 (D. Mass. Sept. 24, 2019), *class decertified by* No. 1:16-cv-12653-ADB, 2020 WL 3840901 (D. Mass. July 8, 2020); *see also* ECF No. 159, ¶ 1(a).

Not surprisingly, defendants in the other actions FWK filed have also sought discovery of those same potentially disqualifying entanglements to test FWK's adequacy to serve as a class

representative. And the few, publicly available (and redacted) transcript excerpts from FWK's own depositions in those other cases show that FWK has testified under oath concerning those very facts and issues. *See, e.g.*, Redacted Tr. of Dep. of Thomas L. Kolschowsky, at 19:25–20:20, 54:14–63:16, *In re Restasis Antitrust Litig.*, 1:18-cv-00677-NG-LB (E.D.N.Y.) (ECF No. 153-5). Defendants now seek production of those transcripts to examine the facts adduced in those depositions concerning FWK's financial entanglements, so they can use them to supplement the documentary discovery received from FWK and to prepare for depositions.

None of the objections FWK has asserted to resist producing the transcripts has merit.

First, the transcripts are undeniably relevant. To serve as a class representative in this case, just as in the other five cases in which it has attempted to serve in the same role, FWK must prove it "will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). This Court has already ruled that the "financial arrangements [between FWK and its counsel] governing this litigation are sufficiently 'entangled' and complex that they can affect the propriety of FWK serving as a class representative." ECF No. 159, at 3. Indeed, the Court relied on the factual overlaps between this case and the others to make its ruling. *Id.* And the publicly available decisions and redacted excerpts from FWK's depositions in the other cases show that the same facts, pertaining to the same issue, adequacy, have been the subject of FWK's sworn testimony in those cases. In short, FWK cannot seriously deny that the transcripts are relevant.

Second, FWK has failed to show (as it must) that producing the transcripts would be unduly burdensome or disproportionate to the needs of this case. Defendants seek only the transcripts of FWK's depositions in five cases. The transcripts should not be hard to find; indeed, all the cases were filed recently—at the same time or after this case was filed; and FWK had the same counsel in those cases as it has in this one. Nor need FWK do anything more than

produce the transcripts. FWK has claimed the transcripts may contain other, confidential information that would be burdensome to redact. But Defendants have no interest in any information peculiar to those other cases; they seek only testimony relating to FWK's ability to serve as an adequate class representative—specifically, FWK's formation, ownership, lenders, business, and operations. And the parties' protective order provides adequate safeguards to protect any other information. So, even assuming FWK may redact other information—a doubtful proposition, *In re Restasis Antitrust Litig.*, 2018 WL 3007926, at *1 (E.D.N.Y. June 4, 2018) ("[a] party should not be permitted to unilaterally decide to redact portions of a responsive document because it determines that they are competitively sensitive and not relevant")—that is a burden of FWK's own making and does not justify withholding the transcripts.

Third, FWK's assertion that protective orders in the other cases may bar production of the transcripts is also unpersuasive. Rare is the protective order that restricts a party from disclosing its own information, as the protective order in the *Zetia* case itself shows. *See* Discovery Confidentiality Order, ¶ 18, *In re Zetia (Ezetimibe) Antitrust Litig.*, 2:18-md-2836 (E.D. Va. Oct. 24, 2018) (ECF No. 171). FWK has not identified any orders that restrict its ability to produce the transcripts in their entirety, much less FWK's own information. Nor has it identified or quantified any burden that might be involved in addressing any such orders.

Finally, FWK's claim that the transcripts are cumulative of documents FWK has produced—and the deposition of FWK that Defendants will take—in this case is also unavailing. To be sure, FWK has produced documents concerning, for example, the financing that its counsel provided to underwrite FWK's purchasing its present claims out of bankruptcy. However, FWK has confirmed that its documentation is incomplete. For example, FWK has not produced, and reportedly does not possess, documents explaining why it repaid that financing

during class discovery in the other cases. Moreover, obtaining transcripts of FWK's past testimony—on the same facts and issues that are relevant to its adequacy to serve as a class representative in this case—could well expedite Defendants' deposition examination and ensure the quality and consistency of FWK's testimony concerning its formation and financial entanglements with its counsel. Not to mention, the transcripts could also be used at trial in this case were FWK to testify inconsistently with its past testimony.

Sanofi has carried its burden to show that the requested transcripts are relevant. *Controlled Kinematics, Inc. v. Novanta Corp.*, No. 17-cv-11029-ADB, 2019 WL 3082354, at *2 (D. Mass. July 15, 2019). FWK has failed to carry its burden to demonstrate that the "requested discovery is [otherwise] improper." *Id.* The Court should order FWK to produce the transcripts.

Plaintiffs' Position

The defendants seek deposition testimony that FWK or its representatives have given in other cases that involve other drugs, other defendants, and other theories of liabilities. But to the extent that those deposition transcripts contain relevant information, FWK has already produced that same information in other forms. As to other information contained in the transcripts, that are specific to the facts and circumstances of each case, that information is subject to protective orders that prohibit disclosure of FWK and other parties' confidential information that may be contained in the transcripts.[1] The request is not proportional to the needs of the case where, as here, documents have been produced on the uncontroverted issues that are a matter of public record and FWK should not be compelled to sift through hundreds of pages and redact what would likely be over 90% of those pages for testimony that the defendants can elicit in this case. Nor is the burden justified simply because the defendants invoke the issue of FWK's adequacy,

[1] The defendants have not sought to modify those protective orders, nor have they asked the plaintiffs to do so.

particularly when no court has used FWK's deposition testimony from another case in rendering an opinion on adequacy.

The defendants seek transcripts and all exhibits from all depositions of FWK or its representatives concerning FWK, its formation, ownership, lenders, business, operations, or adequacy to serve as class representatives. These other cases, however, concern other drugs, other facts, other theories of liability, and thus not discoverable,[2] and are subject to protective orders that prohibit the disclosure of the confidential information from FWK and other parties to the litigation that is contained in the transcripts.[3] The request is thus overly broad and not proportional to the needs of the case given that FWK has already produced the same documents it has produced in other cases from the files of agreed-upon custodians in this case, FWK's ownership and formation are matters of public record, and no court in any case in which FWK has sought to serve as class representative has considered deposition testimony from FWK or its representative given in any other case in determining FWK's adequacy to serve as a class representative. And, in at least one recent case, defendants did not even use FWK's testimony from that case "despite deposing Kolschowsky [FWK's 30(b)(6) representative] with the clear intent of demonstrating FWK's inadequacy[.]"[4]

The defendants' invocation of adequacy does not provide them with a license to seek unfettered discovery or to justify the burden of sifting through what could amount to thousands of deposition transcript pages to identify a few pages of testimony about uncontroverted issues, particularly when Defendants will have an opportunity to depose FWK.

[2] *See Town of Westport v. Monsanto Company*, 2015 WL 13685105, at *3 (D. Mass. Nov. 5, 2015) ("Discovery from prior litigation is discoverable upon showing of substantial similarity between the current and prior litigation.").

[3] Several of the transcripts sought are from resolved or no longer active cases where parsing through what information was and was not confidential would require exhuming closed files.

[4] *In re Zetia Ezetimbe Antitrust Litig.*, 2020 U.S. Dist. LEXIS 112331, at *68 (E.D. Va. June 18, 2020).

Additionally, Defendants have refused to produce deposition testimony of Mr. Freeman in the Zabala deposition "based on the same objections that Plaintiffs have asserted in refusing to produce transcripts of FWK's depositions in other class actions…."[5]

Thus, Defendants' request is simply not proportional to the needs of the case and it cannot justify its need the deposition transcripts.

[5] Letter from T. Martin to B. Vettraino at (Nov. 16, 2021)

PRODUCTION OF SANOFI-NOVO ROYALTY NEGOTIATION DOCUMENTS

Plaintiffs' Position

Sanofi has, but refuses to produce, documents generated during a long-resolved renegotiation of, and arbitration over, the royalty rate Sanofi U.S. would pay Novo Nordisk for the sale of its pen devices, pursuant to a settlement agreement Novo and Sanofi entered following a suit. In that suit, Novo alleged that Sanofi's SoloSTAR pen infringed a Novo pen patent.[6] The requested documents reflect Sanofi's views on (1) the propriety of listing its pen patents in the Orange Book, (2) when it expected follow-on competition, and (3) the impact of those anticipated follow-on competitors—all issues at the heart of this case.[7] Given the context detailed below, one can reasonably expect these renegotiation documents to contain admissions of party-opponent, Sanofi, concerning the royalty rate it believed it should pay to another insulin maker. Sanofi likely anticipated competition before its last Orange-Book listed pen patent expired which would show that the later-expiring pen patents would *not* lawfully keep competitors out of the market. Likewise, statements by Novo—which was bound by the same Orange-Book listing obligations and familiar with the competitive landscape in the insulin space—bear on the reasonableness of Sanofi's pen-patent listing positions in that arbitration and,

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[6] The purchasers' supplemental RFPs requested:

> All documents and communications concerning the re-negotiation of the royalty rate to be paid by Sanofi U.S. to Novo Nordisk in accordance with paragraph 4.6 of the patent infringement settlement dated December 22, 2009 between the two companies, including, but not limited to, any amendments or addenda to the settlement agreement, documents reflecting changes to royalty rate and any tracking of the rate history, and documents and communications concerning the parties' respective positions on the rates, and arbitration-related pleadings, correspondence, and rulings, if any.

Direct Purchasers' Second Set of Requests for Production of Documents to Sanofi-Aventis U.S. LLC, dated July 28, 2021.

[7] For clarity, Sanofi has waived privilege as to the (1) in order to support its "good faith" defense. Sanofi has otherwise produced documents (generated at different time periods and in different contexts) as to (2) and (3).

likewise, here. The purchasers would expect that Sanofi maintains many of these renegotiation documents in a solitary file and could produce them without substantial burden.

Accordingly, the direct purchaser class plaintiffs respectfully request that the Court direct Sanofi to produce these documents, many of which Sanofi could produce easily.

A. The Novo documents are relevant to elements of the purchasers' claims, including market power and antitrust injury, and to Sanofi's regulatory compliance defense.

The Novo documents are relevant to Sanofi's regulatory compliance defense (i.e., whether Sanofi in good faith believed the advice of its counsel), antitrust injury (i.e., the timing of the entry of follow-on products), and market power (i.e., erosion and the impact the loss of exclusivity on Sanofi's SoloSTAR devices had on the market).[8]

Background. In 2007, Novo sued Sanofi alleging that Sanofi's SoloSTAR pen infringed Novo's patent covering Novo's own pen device.[9] Two years later, the parties settled.[10] Under Paragraph 4.6 of their settlement agreement, Sanofi agreed to pay Novo an [redacted] The parties agreed to renegotiate the royalty rate [redacted]

[8] Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]").

[9] SAMA00024165 at -175.

[10] *Id.*

[11] It provides:

[redacted]

[redacted][12] If the parties reached no agreement [redacted] either Sanofi or Novo could initiate arbitration. [redacted][3]

Request. The purchasers seek all non-privileged, responsive documents and communications concerning Sanofi and Novo's negotiations (whether or not made in the actual arbitration) and arbitration materials, including pleadings and submissions, and correspondence and documents exchanged between or among Sanofi and Novo and the arbitrator.

The documents are relevant to Sanofi's good faith beliefs about listing its device patents for SoloSTAR in the Orange Book. The requested documents are relevant to assessing Sanofi's and Novo's views on the merits and propriety of Sanofi's patent listings and ensuing patent litigation relating to those listings. That is: Sanofi's and Novo's views on the legitimacy of Sanofi listing the patent(s) that Novo alleged Sanofi's SoloSTAR pen infringed on Novo's pen device. It is not far-fetched that these discussions could have arisen during settlement negotiations of the original royalty rate in the agreement and then resurface during renegotiation,

[redacted].

Id. at SAMA00024188-89.

[12] *See id.* at -188.

[13] *Id.*

especially because Sanofi's device patents were still listed in the Orange Book at the time.[14] The parties may have even discussed what the industry thought about the legitimacy of Sanofi's listing.

The documents are relevant to the impact the loss of exclusivity on Sanofi's SoloSTAR devices had on the follow-on insulin glargine market. Novo documents are also relevant to the timing of the entry of competitor's follow-on products. Follow-on competitors are likely to come to market at the end of patent expiry. Thus, the renegotiation discussions and arbitration materials could reveal Sanofi's and Novo's views and expectations on the timing of the entry of follow-on competitors and the impact of their entry to Sanofi's SoloSTAR products like Lantus, including Sanofi's and Novo's impressions of the industry's views on entry.

The requested documents would capture the full story on Sanofi's views on the propriety of listing the device patents and the timing of generic entry, connecting any missing links. "The purpose of discovery is to provide a mechanism for making relevant information available to the litigants. 'Mutual knowledge of all the relevant facts gathered by both parties is essential to proper litigation.'"[15] Both Sanofi's and Novo's views are relevant to Sanofi's beliefs about its listing and the timing of entry. Candid statements and submissions by parties in arbitration negotiations are not unusual, as the parties' goal is to achieve faster dispute resolution.[16] To that

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[14] *See*, *e.g.*, *Kajeet, Inc. v. Qustodio*, LLC, No. SA CV181519JAK (PLAx), 2019 WL 8060078, at *12 (C.D. Cal. Oct. 22, 2019) ("It can be inferred from defendant's argument in the relevant Joint Stipulation, however, that defendant possesses additional responsive documents that have been withheld because defendant deemed the documents to be duplicative and/or cumulative . . . .It is not up to one party to decide what its opponent needs to prosecute or defend an action. Moreover, neither the Court nor plaintiff has had any opportunity to review any documents that defendant has deemed cumulative to determine the accuracy of defendant's characterization.").

[15] Fed. R. Civ. P. 26 advisory committee's note to 1983 amendment (quoting *Hickman v. Taylor*, 329 U.S. 495, 507 (1947)).

[16] *See* American Arbitration Association®, *Discovery Best Practices for Construction Arbitration Recommendations for AAA Construction Advocates and Arbitrators* (2021) https://go.adr.org/rs/294-SFS-516/images/AAA341_AAA_Discovery_Best_Practices_Construction_Arbitration.pdf ("The parties should be encouraged to exchange candid statements of claims/damages and counterclaims/damages and defenses to promote full disclosure of disputed issues to expedite the hearings.").

end, admissions, including adopted admissions, commonly ensue.[17] Particularly, in an arms-length negotiation setting between sophisticated companies like Novo and Sanofi, if one party utters a statement relevant to the other parties' interest as to the result of the renegotiation and the other party disagrees, that other party would challenge the statement. Similarly, one party may agree with or admit to certain points made by the other party. Such documents fall within the type of documents the purchasers must see to fully assess Sanofi's regulatory compliance defense and its actual views on the market, including its knowledge of and belief on industry views.

Responsive documents do exist. The purchasers have been pursuing these documents from Sanofi for months, during which time Sanofi U.S.'s own privilege log revealed that responsive documents do exist and that Sanofi's and Novo's negotiations did result in arbitration.[18] Sanofi has not denied the existence of the documents or that arbitration took place. The purchasers used the indication of the documents' existence on the privilege log to begin more productive negotiations on the topic to virtually no avail. Sanofi still refused to conduct a reasonable search. Importantly, the law does not preclude the discovery of arbitration documents, except for documents that the attorney-client privilege independently protects.[19]

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[17] *See* Fed. R. Evid. 801(d)(2); *Universal Am. Barge Corp. v. J-Chem, Inc.*, 946 F.2d 1131, 1142 (5th Cir. 1991) (recognizing that statement uttered in arbitration "may be admissible in the district court over hearsay objection, as statements of a party opponent").

[18] Sanofi's privilege logs dated Feb. 5, 2021 and Apr. 16, 2021 contained no Novo entries, perhaps due to the timing of the parties' service of supplemental requests for production. Then, on Sept. 8, 2021, Sanofi served another revised privilege log with Novo entries appearing on Sanofi's revised log for the first time.

[19] *See Atchison Casting Corp. v. Marsh, Inc.*, 216 F.R.D. 225, 226-28 (D. Mass. 2003) (rejecting confidentiality argument and ordering production of settlement agreement reached through arbitration); *see also Galleon Syndicate Corp. v. Pan Atl. Group*, 223 A.D.2d 510 (1st Dept. 1996) ("There is no confidentiality privilege precluding disclosure of the material requested as the parties to the arbitration proceeding governed by the Rules of the American Arbitration Association are, in the absence of a confidentiality provision, not prohibited from disclosing documents generated or exchanged during the arbitration and since evidentiary material at an arbitration proceeding is not immune from disclosure."); *Kamyr, Inc. v. Combustion Eng'g*, Inc., 161 A.D.2d 233, 554 N.Y.S.2d 619, 620 (1990) ("Evidentiary material at an arbitration proceeding is not immune from disclosure."); *Scott v. Metro. Transp. Auth.*, 10 Misc. 3d

B. The documents are not duplicative; in any event, whether the documents are non-duplicative is not the standard.

Sanofi appears to maintain that the purchasers have no need for the documents because it has already produced documents responsive to other requests by the purchasers that cover the categories of documents the Novo documents fall into, like forecasts. As the purchasers have explained to Sanofi: that is not how discovery works. "It is not up to one party to decide what its opponent needs to prosecute or defend an action."[20] The Federal Rules do not relieve Sanofi of its obligation to produce relevant documents responsive to a document request because it has produced similar documents responsive to other requests. Fed. R. Civ. P. 26 requires relevance and proportionality; nothing else. Under the rule, the purchasers need only show relevance; we do not bear the burden to show proportionality.[21] And, as discussed above, the documents are plainly relevant. The purchasers have not "had any opportunity to review any documents that [Sanofi] has deemed cumulative to determine the accuracy of [Sanofi]'s characterization."[22]

Nonetheless, the documents are not duplicative at all. Sanofi may have produced other materials bearing on expected market entry and the proprietary of listing, but it has not produced these documents in the context of the royalty rate renegotiations or the Novo settlement. The

1058(A), 809 N.Y.S.2d 484 (Sup. Ct. 2005) (requiring production of "all material demanded with respect to the arbitration proceeding").

[20] *See*, *e.g.*, *Atchison Casting Corp. v. Marsh, Inc.*, 216 F.R.D. 225, 227 (D. Mass. 2003) ("[I]t practically goes without saying that [one party] ought not be empowered to decide what may or may not be relevant for [the other's] purposes[.]"); *Kajeet, Inc. v. Qustodio, LLC*, No. SACV181519JAKPLAX, 2019 WL 8060078, at *12 (C.D. Cal. Oct. 22, 2019); Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding *any* nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case.") (emphasis added).

[21] *In re: Bard IVC Filters Prod. Liab. Litig.*, 2016 WL 4943393, at *2 (D. Ariz. Sept. 16, 2016) ("[A]mendment does not place the burden of proving proportionality on the party seeking discovery."); *State Farm Mut. Auto. Ins. v. Fayda*, 2015 WL 7871037, at *2 (S.D.N.Y. Dec. 3, 2015) ("The burden of demonstrating relevance remains on the party seeking discovery, but the newly-revised rule does not place on that party the burden of addressing all proportionality considerations." quotation omitted); *see also Cont'l W. Insur. Co. v. Opechee Constr. Corp.*, 2016 WL 865232, at *1 (D.N.H. Mar. 2, 2016) ("Once a showing of relevance has been made, the objecting party bears the burden of showing that discovery request is improper.").

[22] *Kajeet*, 2019 WL 8060078 at *12.

documents would reveal not only Sanofi's views, but also Novo's views, on whether listing the SoloSTAR or other device patents is proper and the timing of follow-on entry. Sanofi's productions to date do not include documents covering Novo's views or what it (Sanofi) thought about Novo's views. As discussed, parties often exchange candid statements in arbitration negotiations[23] and admissions may ensue.[24] The purchasers are entitled to assess those documents.

C. The documents are proportionate to the needs of this high stakes, law-shaping case.

The purchasers are cognizant that, under Fed. R. Civ. P. 26(b)(1), the parties bear "collective responsibility" to consider proportionality.[25] Despite that responsibility, the burden remains on Sanofi to show disproportionality.[26] This case involves serious allegations about an area of law with little to no case law, i.e., a pharmaceutical company improperly listing device patents in the Orange Book and subsequently suing on those patents in a scheme to restrict

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[23] *See* American Arbitration Association®, *Discovery Best Practices for Construction Arbitration Recommendations for AAA Construction Advocates and Arbitrators* (2021) https://go.adr.org/rs/294-SFS-516/images/AAA341_AAA_Discovery_Best_Practices_Construction_Arbitration.pdf ("The parties should be encouraged to exchange candid statements of claims/damages and counterclaims/damages and defenses to promote full disclosure of disputed issues to expedite the hearings.").

[24] *See Universal Am. Barge Corp.*, 946 F.2d 1131 at 1142 (recognizing that statement uttered in arbitration "may be admissible in the district court over hearsay objection, as statements of a party opponent")

[25] Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment.

[26] *Nerium Skincare, Inc. v. Olson*, No. 3:16-CV-1217-B, 2017 WL 277634, at *3 (N.D. Tex. Jan. 20, 2017) ("a party seeking to resist discovery on these grounds still bears the burden of making a specific objection and showing that the discovery fails the proportionality calculation mandated by [Rule 26] by coming forward with specific information to address [the proportionality factors]…"); *In re: Bard IVC Filters Prod. Liab. Litig*., 2016 WL 4943393, at *2 (D. Ariz. Sept. 16, 2016) ("[A]mendment does not place the burden of proving proportionality on the party seeking discovery."); *see also Cont'l W. Insur. Co. v. Opechee Constr. Corp*., 2016 WL 865232, at *1 (D.N.H. Mar. 2, 2016) ("Once a showing of relevance has been made, the objecting party bears the burden of showing that discovery request is improper.").

competition in violation of antitrust laws. The purchasers' ability to assess these relevant documents outweigh the cost or burden Sanofi would bear to produce them.[27]

It is highly likely that many of these documents are go-get documents, as they likely exist in a centralized source. Thus, production of the arbitration documents at minimum, for example, poses a limited burden on Sanofi.

Defendants' Position

Plaintiffs' request for documents regarding the re-negotiation of a royalty rate Sanofi agreed to pay Novo for use of *Novo's intellectual property* to settle litigation between Sanofi and Novo in 2009 is unduly burdensome, duplicative, and not proportionate to the needs of this case, and should be denied.[28] Plaintiffs first claim the documents are somehow relevant to "the merits and propriety of Sanofi's patent listings and subsequent patent litigation relating to those listings."[29] But the documents Plaintiffs seek pertain to a royalty *for Novo's patents* not Sanofi's patents. Second, Plaintiffs claim the royalty documents "are also relevant to show industry views (including Sanofi's) on the timing of expected market entry by insulin glargine competitors."[30] But even assuming the timing of follow-on insulin glargine competition was part of the negotiation of the

[27] Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment ("It also is important to repeat the caution that the monetary stakes are only one factor, to be balanced against other factors. The 1983 Committee Note recognized 'the significance of the substantive issues, as measured in philosophic, social, or institutional terms. Thus the rule recognizes that many cases in public policy spheres, such as employment practices, free speech, and other matters, may have importance far beyond the monetary amount involved.'").

[28] Specifically, Plaintiffs requested:

> All documents and communications concerning the re-negotiation of the royalty rate to be paid by Sanofi U.S. to Novo Nordisk in accordance with paragraph 4.6 of the patent infringement settlement dated December 22, 2009 between the two companies, including, but not limited to, any amendments or addenda to the settlement agreement, documents reflecting changes to royalty rate and any tracking of the rate history, and documents and communications concerning the parties' respective positions on the rates, and arbitration-related pleadings, correspondence, and rulings, if any. Direct Purchasers' Second Set of Requests for Production of Documents to Sanofi-Aventis U.S. LLC (July 28, 2021) ("Plaintiffs' July 28th RFPs"), Request No. 7.

[29] Letter from Kristen A. Johnson to Julie E. McEvoy (Sept. 27, 2021), at 4.

[30] *Id.*

royalty Sanofi would pay to Novo, Sanofi produced forecasts *directly* showing what Sanofi anticipated the timing and impact of that follow-on entry to be. It is unduly burdensome for Sanofi to identify, collect, and review "any amendments or addenda to the settlement agreement, documents reflecting changes to royalty rate and any tracking of the rate history, and documents and communications concerning the parties' respective positions on the rates, and arbitration-related pleadings, correspondence, and rulings"[31] given that, at best, there may be a smattering of documents among that voluminous collection related to the anticipated entry of follow-on products. In any event, the potential documents would be duplicative of the forecasts that Sanofi *has already produced*. Moreover, as demonstrated by the privilege log in this case, many of the documents related to the timing of follow-on insulin glargine entry are likely to be privileged work product that was prepared at the request of counsel.[32] Thus, Sanofi would be put to the disproportionate burden of collecting, reviewing, and logging tangentially relevant materials even though it has already produced non-privileged forecasts that are directly on point.[33]

Plaintiffs essentially admitted that the request was duplicative when claiming that "purchasers are entitled to seek different types of documents covering the same or similar topics."[34] Nonetheless, Plaintiffs insist that "Sanofi must produce *all* responsive documents on market entry."[35] Plaintiffs are wrong. The Federal Rules are clear that requests for production must be proportionate to the needs of the case, and duplicative documents need not be produced when the same information "is obtainable from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C)(i); *see also* Fed. R. Civ. P. 26(b)(1). Moreover,

[31] Plaintiffs' July 28th RFPs.
[32] *See* Sanofi-Aventis US, LLC October 21, 2021 Revised Privilege Log.
[33] *See id.* Sanofi US confirmed that 45 privilege log entries addressing Novo—which correspond to documents that were collected in response to other document requests—are privileged as the documents were generated at the request of counsel to assist in litigating the Novo dispute. Thus, the documents are subject to the attorney-client privilege as well as the work product protection.
[34] Letter from Kristen A. Johnson to Julie E. McEvoy (Oct. 18, 2021), at 7.
[35] Letter from Kristen A. Johnson to Julie E. McEvoy (Nov. 18, 2021), at 4.

"[t]here is no obligation on the part of a responding party to examine every scrap of paper in its potentially voluminous files, and in an era where vast amounts of electronic information is available for review, . . . courts cannot and do not expect that any party can meet a standard of perfection." *Traverse v. Gutierrez Co.*, No. 18-10175-DJC, 2020 WL9601833, at *3 (D. Mass. Aug. 5, 2020) (quoting *Enslin v. Coca-Cola Co.*, No. 2:14-cv-06476, 2016 WL 7042206, at *3 (E.D. Pa. June 8, 2016) (alterations in original). The Court "must 'limit discovery if it determines that the discovery sought is (1) unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive; (2) the party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or (3) the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the projected discovery in resolving the issues.'" *Lopez v. Uber Techs., Inc.*, No. 1:20-cv-10183-IT, 2021 WL 4267919, at *2 (D. Mass. Sept. 20, 2021) (quoting *In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.*, No. 13-cv-02419, 2014 WL 12814933, at *2 (D. Mass. Feb. 7, 2014)).

Here, Plaintiffs' request for documents regarding the Novo royalty rate negotiations falls squarely within the three criteria in *Lopez*: it is duplicative, obtainable through another source, and unduly burdensome. (1) Sanofi US has already produced documents related to the expected market entry of other insulin glargine products,[36] which Plaintiffs claim is the purpose of the request.[37] Indeed, Sanofi US provided over 40,000 documents from either custodians who were responsible for forecasting or forecasting central sources.[38] Plaintiffs can clearly obtain "the timing of

[36] Letter from Rosanna K. McCalips to Kristen A. Johnson (Sept. 30, 2021), at 4-5.
[37] Letter from Kristen A. Johnson to Julie E. McEvoy (Sept. 27, 2021), at 4.
[38] Letters from Theresa C. Martin to Kristie A. LaSalle (June 4, 2021, June 21, 2021, June 28, 2021), at 1 (producing "forecasting materials responsive to Request Nos. 53, 55, and 58").

expected market entry by insulin glargine competitors"[39] from these documents without unduly burdening Sanofi US with identifying, collecting, reviewing, and logging documents related to a royalty for another company's intellectual property. (2) Plaintiffs have had ample opportunity to obtain information concerning the views of other industry participants as well. In addition to the 40,000 documents Sanofi US produced,[40] Plaintiffs have subpoenaed other pharmaceutical stakeholders directly regarding their views on expected market entry.[41] (3) The burden or expense of the proposed discovery outweighs its likely benefit. There is no logical connection between royalties Sanofi US paid *to Novo* for a license *on Novo's patents* and the propriety of Sanofi US submitting information regarding *Sanofi's own patents* to the FDA for inclusion in the Orange Book.[42] While Sanofi's views on the timing and effect of follow-on competition is relevant, Sanofi has already produced documents that show this *directly*. Allowing Plaintiffs to put Sanofi US to the burden of sifting through documents from an unrelated legal proceeding to find snippets that may, or may not, shed light on the anticipated timing of follow-on glargine competition would be the definition of undue burden and disproportionality. Plaintiffs' request to compel Sanofi to produce Novo royalty documents in response to Request No. 7 of Plaintiffs' July 28th RFPs should be denied.

[39] Letter from Kristen A. Johnson to Julie E. McEvoy (Sept. 27, 2021), at 4.
[40] Letter from Theresa C. Martin to Kristie A. LaSalle (June 21, 2021), at 1.
[41] *See, e.g.*, Notice of Subpoenas to Eli Lilly & Co., Merck & Co., and Mylan Pharmaceuticals, Inc. from Direct Purchasers (July 27, 2020).
[42] Letter from Rosanna K. McCalips to Kristen A. Johnson (Nov. 3, 2021), at 6.

Dated: December 3, 2021

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CERTIFICATE OF SERVICE

I, Theresa C. Martin, hereby certify that a true copy of the foregoing document filed through the ECF system will be electronically sent to the registered participants as identified on the Notice of Electronic Filing on December 3, 2021.

/s/ Rosanna K. McCalips
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